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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Karl-Hermann Schlingensiepen

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EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,879	Applicant(s) SCHLINGENSIEPEN ET AL.	
	Examiner TERRA C. GIBBS	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008 and 08 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's Election filed September 22, 2008 and Applicant's Amendment and Remarks filed April 8, 2008.

Claims 1, 4-7, 12-14, 16, and 17 have been amended.

Claims 1-17 are pending in the instant application.

This application contains claims 7 and 12-14 drawn to an invention nonelected without traverse in the reply filed on September 22, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Election/Restrictions

Applicant's election of Group I, claims 1-6, 8-11, and 15-17 in the reply filed on September 22, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7 and 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As noted above, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse.

Applicant is reminded that the Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a

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product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note

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that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Accordingly, claims 1-6, 8-11, and 15-17 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Nucleotide Sequence Disclosures

In the previous Office Action mailed October 12, 2007, it was noted that the instant application failed to comply with the requirements of 37 C.F.R. §1.821-1.825. It is also noted that in Applicant's Reply filed on April 8, 2008, Applicants amended the disclosure to accompany nucleic acid sequences with SEQ ID NOs. In view of this reply, the instant application is fully compliant with the sequence requirements of 37 C.F.R. §1.821-1.825.

Specification

In the previous Office Action mailed October 12, 2007, the disclosure was objected to because it did not comply with the requirements of 37 CFR § 1.74. It is noted that in Applicant's Reply filed on April 8, 2008, Applicants amended the disclosure to reference the drawings. In view of this reply, the instant application is fully compliant with the requirements of 37 CFR § 1.74.

Drawings

In the previous Office Action mailed October 12, 2007, the drawings were objected to as failing to comply with 37 CFR 1.84(p)(5). It is noted that in Applicant's Reply filed on April 8, 2008, Applicants amended the disclosure to include a brief description of the drawings. In view of this reply, the instant application is fully compliant with 37 CFR 1.84(p)(5).

Claim Rejections - 35 USC § 101

In the previous Office Action mailed October 12, 2007, claims 7 and 12-14 were rejected under 35 U.S.C. 101 because the claims recited recitation of a use, without setting forth any steps involved in the process. **This rejection is withdrawn** in view of Applicant's Amendment filed April 8, 2008. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claims 7 and 12-14 to recite that these claims are drawn to methods of use, instead of just a recitation of use.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed October 12, 2007, claims 4-7, 12-14, 16 and 17 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicant's Amendment filed April 8, 2008. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to correct for a lack in antecedent basis. Further,

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this rejection is withdrawn in view of Applicant's Amendment to the claims to set forth steps involved in the method(s).

Claim Rejections - 35 USC § 102

In the previous Office Action mailed October 12, 2007, claims 1, 4-6, 8-11, and 15-17 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65928 A2.

This rejection is maintained for the reasons of record set forth in the previous Office Action mailed October 12, 2007.

In the previous Office Action mailed October 12, 2007, claims 1, 5, 6, 8, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/77384 A2. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed October 12, 2007.

Response to Arguments

In response to these rejections, Applicants argue that the individual sequences disclosed by WO 99/65928 and WO 01/77384 are not fragments of SEQ ID NO:1. For example, Applicants argue that there is a difference between C and G at position 10 in the sequence disclosed by the WO 99/65928 document; and there is a difference between A and G at position 12 in the sequence disclosed by the WO 01/77384 document. These arguments have been fully considered, but are not found persuasive because contrary to Applicant's arguments, the sequences disclosed by WO 99/65928

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and WO 01/77384 are indeed fragments of SEQ ID NO:1. For example, the sequence disclosed by WO 99/65928 consists of a 9 base pair fragment of SEQ ID NO:1. See specifically AAA CCC AAG. Similarly, the sequence disclosed by WO 01/77384 consists of an 11 base pair fragment of SEQ ID NO:1. See specifically CAT AAA CCC AA

It should be noted that Applicants have not defined the term, "fragment". However, Applicant's specification discloses:

"It is also understood by persons skilled in the art that fragments having subsequences of the above given antisense oligonucleotide with at least 8 nucleotides or modifications thereof work according to the invention so long as production of MIA is reduced or inhibited."

Therefore, absent a specific definition of the term, "fragment", it is the Examiner's position that the sequences disclosed by WO 99/65928 and WO 01/77384 consists of fragments of SEQ ID NO:1 as claimed in Applicant's invention.

Therefore, absent evidence to the contrary, claims 1, 4-6, 8-11, and 15-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65928 A2 and claims 1, 5, 6, 8, and 15-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/77384 A2.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed October 12, 2007, claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/65928 A2 (Reference A.M on Applicant's Information Disclosure Statement filed February 9, 2006) in view of WO

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01/68122 (Reference A.L. on Applicant's Information Disclosure Statement filed February 9, 2006). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed October 12, 2007.

Response to Arguments

In response to these rejections, Applicants argue that the sequence disclosed by WO 99/65928 is not a fragment of SEQ ID NO:1. For example, Applicants argue that there is a difference between C and G at position 10 in the sequence disclosed by the WO 99/65928 document. These arguments have been fully considered, but are not found persuasive because contrary to Applicant's arguments, the sequence taught by WO 99/65928 is indeed a fragment of SEQ ID NO:1. For example, the sequence taught by WO 99/65928 consists of a 9 base pair fragment of SEQ ID NO:1. See specifically AAA CCC AAG.

It should be noted that Applicants have not defined the term, "fragment". However, Applicant's specification discloses:

"It is also understood by persons skilled in the art that fragments having subsequences of the above given antisense oligonucleotide with at least 8 nucleotides or modifications thereof work according to the invention so long as production of MIA is reduced or inhibited"

Therefore, absent a specific definition of the term, "fragment", it is the Examiner's position that the sequences taught by WO 99/65928 consists of fragments of SEQ ID NO:1 as claimed in Applicant's invention.

Therefore, absent evidence to the contrary, claims 1-3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/65928 A2 in view of WO 01/68122.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

December 18, 2008

/Terra Cotta Gibbs/

/Sean R McGarry/

Primary Examiner, Art Unit 1635